

1091866

510(k) Summary

as required by CFR section 807.92(c)

JUL 20 2009

I. General Information

Date: June 4, 2009

Applicant: Midmark
675 Heathrow Dr.
Lincolnshire, Ill.
60069

Contact Person: Alan Krema

Telephone: 847-415-9800 x785

Fax: 847-415-9801

II. Names

Device Name:

Trade Name: Progeny Vantage Panoramic X-Ray System
Common Name: Panoramic X-Ray System
Classification Name: MUH – Unit, X-Ray, Extra oral with Timer

III. Predicate Devices

#K011619	Planmeca Promax
#K992385	Instrumentarium Orthopantomograph OP100D
#K050255	Gendex Orthoralix 8500

Product Description

The Progeny Vantage Panoramic X-ray System is an extraoral radiographic imaging system for producing digital radiographs in a panoramic view of the teeth, jaw, and oral structure.

The Progeny Vantage Panoramic Extraoral Radiographic Imaging System consists of the following main components:

- X-ray tubehead with integrated collimation.
- Digital Image Receptor
- Rotating C-Arm for tubehead and image receptor mounting
- Overhead arm
- Elevating Column
- Patient Positioning Table
- Electronic Control Unit
- Computer Display Workstation
- 8 ft. coil cord with exposure switch

Optional Components: None

V. Indications for Use / Rationale for Substantial Equivalence

Indications For Use of the Progeny Vantage Panoramic X-Ray System:

The indications for use of the Progeny Vantage Panoramic Extra Oral X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. As a digital device, the images are displayed on a monitor. The Image management software, including any image manipulation, archiving, and communication are not a part of this device.

The Vantage shares the same indications for use, materials, design, operational and functional features and is therefore substantially equivalent to the predicate devices listed in section III of this summary.

The Progeny Panoramic Radiographic Imaging System is similar in design, composition, and function to the following devices introduced into commercial distribution after May 28, 1976:

#K011619	Planmeca Promax
#K992385	Instrumentarium Orthopantomograph OP100D
#K050255	Gendex Orthoralix 8500

Labeling for the currently marketed devices is included as Appendix B.

Comparison Table

Characteristic	PlanMeca Promax	Gendex 8500	Instrumentarium OP200D	Progeny Vantage
kVp	60-84 kVp	60-80 kVp	57-85 kVp	60-84 kVp
mA	1-16 mA	4-10 mA	2-16 mA	4-10mA
Digital Sensor	Y	Y	Y	Y
Image Pixel size	66µm	96 µm	96 µm	96 µm
Exposure Time	2-17s	11-12s	12s	8-10s
Image Profiles	Pan, TMJ, Ortho	Pan	Pan, TMJ, Ortho	Pan, TMJ, Ortho
Operator Exposure Control	Deadman Switch	Deadman Switch	Deadman Switch	Deadman Switch
User Interface	Color Touch Screen	Keypad and LED Display	Color Touch Screen	Color Touch Screen
X-Ray tube focal spot	0.5mm ²	0.4mm ²	0.5mm ²	0.5mm ²
Magnification	1.2	1.25	1.3	1.2
Column	Telescoping	Telescoping	Fixed	Telescoping
Construction	Aluminum castings with plastic and metal covers	Aluminum extrusions with plastic covers	Aluminum castings with plastic and metal covers	Aluminum castings with plastic and metal covers

The predicate devices show a range of specifications. The Progeny Vantage is equivalent to at least one of the predicate devices for each of the specifications excepting exposure time. The shaded areas in the table above show the areas of congruence. Exposure time, by itself, is not a critical specification for comparison, as the equivalence in sensors across two of the predicate devices indicates a similar dose to achieve the same level of image detail.

VI. Safety and Effectiveness Information

Safety and effectiveness is demonstrated by:

- Performance testing and verification to meet product specifications.
- Software testing to validate software design and performance.
- Hazard analysis and risk level assessment.
- Same indications for use as predicate devices.

All of the above steps and evaluations combine to demonstrate that the Panoramic Extraoral Radiographic Imaging System is safe and effective when the device is used as labeled.

VII. Conclusion

The Progeny Vantage Panoramic Extraoral Radiographic Imaging System is determined to be substantially equivalent to the predicate devices, the Planmeca Promax, the Instrumentarium Orthopantomograph OP100D, and the Gendex. The Panoramic Extraoral Radiographic Imaging System shares the same indications for use, materials, design, operational and functional features to the currently marketed predicate devices listed in section III of this summary. The Panoramic Extraoral Radiographic Imaging System is safe and effective when the device is used as labeled.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2009

Midmark
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091866

Trade/Device Name: Progeny Vantage Panoramic X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: July 8, 2009
Received: July 9, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

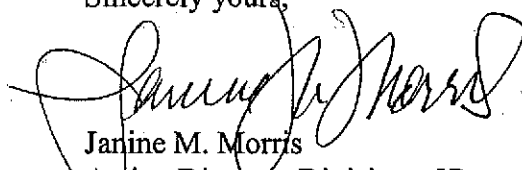
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOoffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K091866

Device Name:

Progeny Vantage Panoramic X-Ray System

Indications For Use:

The indications for use of the Progeny Vantage Extra-Oral Panoramic X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

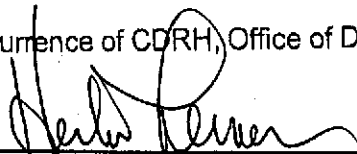
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

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